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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,257	03/09/2005	Jun Wu	186353/US	5292

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DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
SUITE 1500
50 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402-1498

EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,257	WU ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/20/06*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12 are all the pending claims for this application and that are subject to restriction.

2. The Examiner gratefully acknowledges Applicants filing the Supplemental Response of December 20, 2006 submitting the revised Sequence Listing, CRF and statement, which have been considered and entered. In view of the Examiner's sequence search for SEQ ID NO:2 based on the revised Sequence Listing, the previous Office Action of 11/6/06 is hereby vacated.

3. A sequence search of SEQ ID NO:2 and amino acid residues 29-213 of SEQ ID NO:2 was performed in commercial protein databases and a post-filing date reference, Strausberg et al. (PNAS 99:16899-16903 (December 2002)), was found to disclose a 213 amino acid residue protein having 99.5% identity with SEQ ID NO:2, and a fragment having 100% sequence identity with amino acid residues 29-213 of SEQ ID NO:2. See the attached copies of the protein sequence search alignments.

4. On the basis of the sequence search results for the protein sequence, the claims appear to recite a common special technical feature which is the protein of SEQ ID NO:2.

5. Restriction is required under 35 U.S.C. 121 and 372.

Group I, claim(s) 1 and 2, drawn to a human RL5 protein of SEQ ID NO:2 or amino acid residues 29-213 of SEQ ID NO:2.

Group II, claim(s) 3, 4 and 6-8, drawn to a polynucleotide encoding the human RL5 protein of SEQ ID NO:2 or amino acid residues 29-213 of SEQ ID NO:2, vectors, vector engineered host cells, and methods of producing the protein from the vector engineered host cell.

Group III, claim(s) 9, 11 and 12, drawn to an antibody that specifically binds the human RL5 protein of SEQ ID NO:2 or amino acid residues 29-213 of SEQ ID NO:2, and pharmaceutical compositions thereof.

Group IV, claim(s) 11 and 12, drawn to a pharmaceutical composition comprising an antisense nucleotide sequence for RL5 gene.

Group V, claim(s) 10, drawn to a method of detecting a RL5 protein in a sample using an antibody against RL5 and observing an immunecomplex.

The inventions are distinct and separate for the following reasons:

6. Four different products are presented in Groups I-IV. These products do not share a common core structure, nor common property or activity. A nucleic acid structure of Group II or IV is comprised of linear, contiguous nucleotides while a protein's structure of Groups I and III is comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the nucleic acid's function is to encode a protein, the antisense nucleotide is to hybridize to a specific gene or transcript, while a protein's function is variable. Additionally, the nucleic acids, antisense nucleotides and polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the nucleic acids and polypeptides have materially different functions as noted above.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Groups I and III, restriction for examination purposes as indicated is proper. For example, claims in Group I, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleic acid sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups II and IV and Groups I and III have been appropriately restricted on the basis of being distinct.

With respect to the proteins of Groups I and III the RL5 polypeptide has a function as a tumor-specific rejection antigen (p. 12, line 18 of the specification) while the antibody binds to the polypeptide with a specific affinity and avidity. Each of the proteins would have different amino acid sequences and folded structures. Thus, Groups I and III have been appropriately restricted on the basis of being distinct. The examination of all groups would require different searches in the U.S. and foreign patent literature and the scientific literature and would require the consideration of different patentability issues.

7. Inventions of Group III and Groups V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibody could be used to purify the protein by immunoaffinity chromatography or it could be used as a therapeutic alone or conjugated to other therapeutic agents for specific cell targeting. The examination of all groups would require different searches in the U.S. and foreign patent literature and the scientific literature and would require the consideration of different patentability issues.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER